> the latent nature of the damage allegedly caused by PFRI, the former owner of [plaintiff] Sebago's building cannot reasonably be described as having been directly injured. Rather, the plaintiffs as present owners of buildings with alleged structural damage caused by PFRI's latent defects can be said to have been "truly injured in some meaningful sense." As such, allowing plaintiffs to press their claims here will further RICO's statutory goal of encouraging directly injured victims to act as private attorneys general to vindicate the law.

Id. at 83 (quoting *Holmes*, 503 U.S. at 279 (O'Connor, J., concurring).

Reading the allegations of the complaint, Judge Wolf found that the plaintiff owners had alleged that they were among the "intended victims" of the defendants' scheme to defraud. *Id.* at 83-84. Thus, assuming (as we must) that Defendants "have committed the acts alleged,"

> it is for a jury to apply the law of proximate ***causation*** and decide whether the plaintiffs were in the zone of foreseeable plaintiffs and whether the defendants' actions were a substantial factor in causing the plaintiffs' harm. *Peckham v. Continental Cas. Ins. Co.*, 895 F.2d 830, 837 (1st Cir. 1990) (holding that questions of ***causation*** "are normally grist for the jury's mill."); *Swift v. United States*, 866 F.2d 507, 510 (1st Cir. 1989) ("Application of the legal cause standard to the circumstances of a particular case is a function ordinarily performed by, and peculiarly within the competence of, the factfinder."); W. Prosser & W. Keeton, Prosser and Keeton on Torts 321 (5th ed. 1984) ("'proximate cause is ordinarily a question of fact for the jury, to be solved by the exercise of good common sense in the consideration of the evidence of each particular case.'") (citation and footnotes omitted). Thus, the court cannot properly rule as a matter of law that plaintiffs were outside the zone of foreseeable plaintiffs or that the defendants' actions were not a substantial factor. To the contrary, accepting the plaintiffs' allegations as true and drawing all reasonable inferences from them, it appears that both plaintiffs were among the intended victims of the alleged fraud. For purposes of these motions to dismiss, therefore, plaintiffs adequately plead ***causation*** and state a substantive RICO claim.

18 F. Supp. 2d at 85 (emphasis added).[30] The same principles apply in this case, and this Court should reject Defendants' contention that Plaintiffs do not properly alleged RICO standing.

[30] Defendants also argue that Plaintiffs should be barred from recovery because they are supposedly "indirect purchasers" of the Covered Drugs. Defs.' Memo. at 23. Even if it can be said that civil RICO liability "stops at the first victim," *Wooten v. Loshbough*, 951 F.2d 768, 770 (7th Cir. 1991), Plaintiffs allege that ***they*** are the "first" victims of the AWP Scheme; they are "out of pocket" as a consequence of Defendants' wrongdoing. *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 475 (1982). In any event, the antitrust "indirect purchaser" doctrine does not bar Plaintiffs' claims against Defendants. *See Managed Care Litigation*, 185 F. Supp. 2d at 1319-20; *Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris, Inc.*, 29 F. Supp. 2d 801, 823-24 (N.D. Ohio 1998).

H. Plaintiffs Properly Assert RICO Conspiracy Claims Against Defendants

Count I alleges a violation of RICO § 1962(d) because "each [Defendant] and each of the providers that were members of the AWP Enterprises ***conspired*** to conduct the affairs of such enterprises through [a] pattern of racketeering activity. . . ." ¶ 358 (emphasis added). In a footnote, defendants assert that Plaintiffs fail to allege that Defendants "knowingly" joined the conspiracy. Defs.' Mem. at 35 n.29. However, it is not necessary for Plaintiffs to allege that each of the Defendants "knew all the details or the full extent of the conspiracy, including the identity and role of every other conspirator." *Aetna*, 43 F.3d at 1562. Rather:

> All that is necessary to prove [a RICO conspiracy] is to prove that [defendant] agreed with one or more co-conspirators to participate in the conspiracy. Moreover, it is not necessary for the conspiratorial agreement to be express, so long as its existence can plausibly be ***inferred*** from words, actions, and the interdependence of activities and persons involved. In this case, the jury reasonably could have found that, although each defendant may not have known the entire sweep of the conspiracy, each defendant knew that he or she was a part of a larger fraudulent scheme. For example, since the evidence supported a finding that each of the Aetna defendants was well aware of the fraudulent business practices of Dexter and Cummings, the jury could find that all of the Aetna defendants knew they were part of a larger conspiracy in which other persons made uses similar to their own of fraudulent appraisals by Dexter, Cummings, or both.
>
> A defendant who does not know the "entire conspiratorial sweep" is nevertheless jointly and severally liable, in the civil context, for all acts in furtherance of the conspiracy.

Id. at 1562 (citation omitted) (emphasis added); *see also United States v. Boylan*, 898 F.2d 230, 242 (1st Cir. 1990).

Similarly, the Complaint alleges that each Defendant was aware of the AWP Scheme involving the fraudulent reporting of AWPs to the Publishers. Based upon these allegations, a jury can find that each Defendant knew that it was part of a larger conspiracy in which other companies made "uses similar to their own" of false and misleading AWPs. *Id.* Thus, under First Circuit precedent, Plaintiffs properly allege a RICO conspiracy claim against Defendants.

VII. PLAINTIFFS' STATE LAW CLAIMS ARE NOT PREEMPTED

Count V alleges that Defendants violated the consumer protection statutes of eleven states. ¶¶ 451-57. Defendants argue that (i) to the extent the Plaintiffs paid through the Medicare system, these state law claims are preempted by the Medicare Act and its regulations, and (ii) to the extent the Plaintiffs paid through an ERISA plan, the claims are preempted by the Employee Retirement Income Security Act ("ERISA"). Defs.' Mem. at 35. However, these challenges fail.

A. The Medicare Act Does Not Preempt Plaintiffs' Claims

In evaluating preemption, the "sole task" of a reviewing court is to determine the intent of Congress, *California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 280 (1987), beginning with the basic assumption that Congress ordinarily does ***not*** intend to displace state law. *See, e.g., Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *see also Massachusetts Ass'n of HMOs v. Ruthardt*, 194 F.3d 176, 178-79 (1st Cir. 1999). This is especially true where, as here, the claims involve an area traditionally regulated by the police power of the state such as the regulation of healthcare, including medical costs. *See Pennsylvania Med. Soc'y v. Marconis*, 942 F.2d 842, 846-7 (3d Cir. 1991); *Massachusetts Med. Soc'y v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (the field of medical fee regulation seems by tradition to be one of state concern, and accordingly state laws regulating that area are presumed constitutionally valid); *Medical Soc'y of New York v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992) (stating that the "regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state" and requiring "compelling evidence of an intention to preempt").

1. The Medicare Act Does Not Preempt The Field

Defendants' argument of field preemption is belied by three controlling precedents from the First, Second and Third Circuits. In *Massachusetts Med. Soc'y*, the First Circuit addressed the preemptive effect of Medicare Part B on state statutes regarding balanced billing and found that the federal statute demonstrated an explicit intent to ***minimize*** federal intrusion and ***not*** to preempt. *Id.* at 790-91. Similarly, in *Pennsylvania Med. Soc'y*, 942 F.2d at 846, the Third

Circuit held that Medicare Part B did not preempt state legislation regulating the medical billing practices. In *Medical Soc'y of New York*, 976 F.2d 816, the Second Circuit held that Medicare Part B had no preemptive effect on New York law capping physicians' fees. *See also Solorvano v. Superior Court*, 10 Cal. App. 4th 1135, 1146 (2d Dist. 1992) (holding that Medicare does not preempt state law fraud and unfair business practices claims).

Defendants errantly contend that Congress intended to occupy the field of Medicare drug reimbursement through a "pervasive, extensive and detailed" regulatory scheme. Defs.' Mem. at 36-37. To support their contention, Defendants again argue that Plaintiffs' seek to have state law define AWP, *see* Defs.' Mem. at 36-37, but as demonstrated *supra*, Plaintiffs merely seek to redress Defendants' wrongful scheme of deliberately ***inflating*** the AWPs of their drugs at the expense of Plaintiffs and the Class.

Moreover, the text of Medicare Part B reveals that it was not intended to displace state law because it lacks enforcement mechanisms for defrauded beneficiaries. In the absence of any federal remedy, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) (finding that even though states are precluded from regulating the safety aspects of nuclear energy, state tort law remedies for personal injury are not preempted). In fact, the only sanctions specifically detailed under the Act explicitly preclude any preemptive effect by stating that the federal remedy is ***supplemented*** by sanctions available under state law. 42 U.S.C. § 1395 w-2. There is simply no indication that Congress intended to preclude the use of state law remedies for acts of fraud.

Courts also have found that, in passing the Medicare Act, Congress specifically intended to minimize federal intrusion into areas of state concern. *See Massachusetts Med. Soc'y*, 815 F.2d at 791. Indeed, the rights of citizens to bring consumer protection claims have long been established, and issues concerning health care, including health care fraud and the cost borne by consumers, have long been within the purview of the states. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (stating that "the regulation of health and safety

matters is primarily, and historically, a matter of local concern"); *Med. Soc'y of New York*, 976 F.2d at 816 (finding that the "regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state").

Furthermore, the Medicare Act has been the subject of constant review and modification since its passage in 1965. Since that time, Congress has never amended Medicare to take away from the states the rights to protect their citizens through common law fraud or consumer protection claims. *See Pennsylvania Med. Soc'y*, 942 F.2d at 850 ("[W]hen Congress remains silent regarding the preemptive effect of its legislation on state laws it knows to be in existence at the time of such legislation's passing, Congress has failed to evince the requisite clear and manifest purpose to supersede those state laws") (citations omitted). Thus, this silence is strong evidence negating Congressional intent to preempt.[31]

Like the defendants in *Massachusetts Med. Soc'y*, Defendants have failed to demonstrate a clear and manifest Congressional purpose to preempt state law. Both textual and case analysis compel the conclusion that Congress did not occupy the field covered by Medicare Part B to the exclusion of areas of traditional state concern, such as state deceptive trade practice statutes.

2. Plaintiffs' Claims Do Not Conflict with the Medicare Act

Defendants contend that Plaintiffs' state law claims conflict with the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA") because "plaintiffs are asking the Court under state laws. . . to substitute different AWPs." Defs.' Mem. at 37. The argument misrepresents the terms of BIPA and ignores the law on conflict preemption.

Conflict preemption exists when compliance with both state and federal law is impossible, or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. National Foreign Trade Council*, 530

[31] Nor does the one case cited by Defendants, *Congress of Cal. Seniors v. Catholic Healthcare West*, 87 Cal. App. 4th 491 (2d Dist. 2001), suggest otherwise. Defs.' Mem. at 37 n.31. First, unlike here, the case dealt with Medicare Part A, and not Medicare Part B. Second, the court's conclusion that federal law comprehensively occupied the field of Medicare provider cost reporting and reimbursement involved a vast web of statutes and regulations under Part A that are not present here. Third, Plaintiffs' claims do not require proof of a violation of a federal statute or a reexamination of agency rulemaking.

U.S. 363, 373 (2000). An actual conflict must exist for a finding of preemption; hypothetical or potential conflicts are insufficient. *See Rice v. Norman Williams Co.*, 458 U.S. 654 (1982).

Here, Defendants' preemption argument rests entirely on a misreading of BIPA. BIPA did not, as Defendants represent, "prevent HCFA from recasting AWP" or "prohibit HCFA from changing this system of reimbursement." Defs.' Mem. at 36. In fact, in BIPA Congress expressly authorized HCFA to "revise the payment methodology . . . for drugs and biologicals under part B of the medicare program" so long as it did so on the basis of recommendations following a GAO report. Defendants' Exhibit 16 at 160. BIPA sanctions HCFA review and alteration of the AWP system; it does not prevent it.

Moreover, nothing in BIPA can arguably conflict with the traditional police powers of the state to regulate health care and medical costs, or protect citizens from unscrupulous business conduct. Plaintiffs do not seek to substitute AWPs with arbitrary ones. Nor does requiring manufacturers to report accurate AWPs impede Medicare's objectives. To the contrary, it advances the objective of maintaining the financial integrity of the system.[32]

B. ERISA Does Not Preempt Plaintiffs' State Law Claims

Defendants contend that ERISA preempts the consumer protection claims of the plaintiff third-party payors, as well as the claims of individual Plaintiffs whose co-payments were made by an ERISA plan because, ostensibly, these state law claims "relate to" employee benefit plans. Defs.' Mem. at 37-40. Defendants misconstrue ERISA preemption law.

ERISA expressly preempts state laws that "***relate to*** any employee benefit plan." 29 U.S.C. § 1144(a) (emphasis added). Although courts have liberally interpreted the phrase "relate to" as meaning having a "connection with" or "reference to" an employee benefit plan (*see, e.g., California Div. of Labor Stds. Enforcement v. Dillingham Constr.*, 519 U.S. 316, 324 (1997)), "ERISA preemption is not inexorable." *Carpenters Local Union No. 26 v. United States Fid. & Guar. Co.*, 215 F.3d 136, 139 (1st Cir. 2000). In fact, the United States Supreme Court

[32] *See TAP Pharms. v. U.S. Dept. of Health & Human Services*, at 163 F.3d 199, 204 (4th Cir. 1998).

recognized that "relate to" was being interpreted well beyond that intended by Congress and consequently held that state laws that only ***indirectly*** relate to ERISA plans are not preempted: "***pre-emption does not occur . . . if the state law has only a tenuous, remote, or peripheral connection with covered plans, as is the case with many laws of general applicability***." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995) (quoting *District of Columbia v. Greater Washington Bd. of Trade*, 506 U.S. at 130, n.1) (emphasis added).[33]

The First Circuit's recent decision in *Carpenters Local* demonstrates the controlling distinction. The employees of a subcontractor (and their union) brought a state court action against a general contractor's surety to recover on a bond. 215 F.3d at 138. The claim arose because the subcontractor failed to make fringe benefit payments as required under Massachusetts' bond statute. *Id.*[34] The court reviewed several factors used to determine whether the law had a meaningful "connection with" with ERISA, namely whether the law (i) interferes with the administration of covered employee benefit plans; (ii) purports to regulate plan benefits; (iii) purports to impose additional reporting requirements; or (iv) regulates an area of the law traditionally thought to be the states' preserve. *Id.* at 141. Applying these factors, the court held that the bond statute did not have a meaningful "connection with" ERISA because the law had "no real bearing on the intricate web of relationships among the principal players in the ERISA scenario (*e.g.*, the plan, the administrators, the fiduciaries, the beneficiaries, and the employer)." *Id.* at 141. Furthermore, the statute did not "refer to" ERISA because the state law did not single out ERISA plans for special treatment and did not depend "on their existence as an essential part of its operation." *Id.* at 145.

[33] At issue was whether a state statute regulating hospital rates for inpatient care was preempted. The court found that "cost uniformity was almost certainly not an object of pre-emption, just as laws with only an indirect economic effect on the relative costs of various health insurance packages in a given State are a far cry from those 'conflicting directives' from which Congress meant to insulate ERISA plans." *Id.* at 662.

[34] The bond statute required the general contractor to post a bond covering labor and materials, including any indebtedness incurred by subcontractors for wages and fringe benefits. *Id.* at 139.

Applying *Carpenters Local* here demonstrates that Plaintiffs' state law claims do not have a "connection with" an employee benefit plan. With respect to the first three inquires in the *Carpenters Local* test, the consumer protection claims do ***not*** interfere with the administration of any employee benefit plan, regulate plan benefits or impose additional reporting requirements. Plaintiffs do ***not*** dispute the terms or scope of any benefit plan, seek to enforce benefits under ERISA plans, or claim that Defendants failed to provide benefits. To the contrary, Plaintiffs seek only to recover from Defendants co-payments fraudulently inflated by Defendants' AWP scheme in violation of consumer protection statutes. Any damages would come from Defendants and not from the plan itself. Thus, Plaintiffs' claims would not impact the structure of the plan nor have a demonstrable economic impact on the plan. Turning to the fourth prong, state consumer protection laws against fraud regulate "an area traditionally thought to be the states' preserve." *See, e.g., Trustees of the AFTRA Health Fund v. Biondi*, 303 F.3d 765, 775 (7th Cir. 2002); *LeBlanc v. Cahill*, 153 F.3d 134 (4th Cir. 1998).[35]

Nor do Plaintiffs' claims "refer to" ERISA per *Carpenters Local*. The relevant consumer protection laws do not single out ERISA plans for special treatment but apply generally to all fraudulent acts that harm consumers. Furthermore, consumer protection statutes do not depend on the existence of the ERISA plans as an essential part of their operation. Accordingly, ERISA does not preempt Plaintiffs' state law claims.[36]

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[35] Indeed, courts consistently permit state law claims by service providers against plans and insurers who pay plan benefits of plans who misrepresent coverage or the amount of benefits, wrongfully inducing health care providers to provide services. *See, e.g., In Home Health v. Prudential Ins. Co. of Am.*, 101 F.3d 600 (8th Cir. 1996); *The Meadows v. Employers Health Ins.*, 47 F.3d 1006 (9th Cir. 1995); *Lordmann Enters., Inc. v. Equicor, Inc.*, 32 F.3d 1529 (11th Cir. 1994); *Hospice of Metro Denver, Inc. v. Group Health Ins.*, 944 F.2d 752 (10th Cir. 1991); *Memorial Hosp. Sys. v. Northbrook Life Ins. Co.*, 904 F.2d 236 (5th Cir. 1990); *but see Cromwell v. Equicor-Equitable HCA Corp.*, 944 F.2d 1272 (6th Cir. 1991).

[36] Defendants cite *Harris v. Harvard Pilgrim Health Care, Inc.*, 208 F.3d 274 (1st Cir. 2000), for the proposition that ERISA preempts state law claims where the court must consult the terms of the ERISA plans to resolve plaintiffs' claims. Defs.' Mem. at 39 n.34. *Harris*, however, is inapposite because there, the court preempted a state action that could have interfered with the enforcement of the plan as against a participant. By contrast, no such "core" purpose is compromised here, where the plans are suing parties outside the ERISA plans to remedy fraud. *Harris* does not help revive Defendants' claim to ERISA preemption. Further, Defendants' argument that plaintiffs' claims are preempted because the court must consult the terms of the ERISA plans "to determine whether and how certain plaintiffs were injured" is baseless. Defs.' Mem. at 39. *See Stetson v. PFL Ins. Co.*, 16 F. Supp. 2d 28 (D. Me. 1998) (rejecting defendant's argument that fraud claim is preempted because determining the claim's validity required reference to the terms of employee benefit plan).

VIII. THE REMAINING ARGUMENTS MADE BY INDIVIDUAL DEFENDANTS DO NOT WARRANT DISMISSAL

In separate briefs, certain individual defendants have presented a potpourri of additional arguments in support of dismissal. Some, but not all, of these additional arguments have been addressed *supra*. Those that have not are addressed below.

A. Plaintiffs Have Standing To Sue All Defendants

Twenty-one (21) of thirty-seven (37) defendants[37] seek dismissal of all or some claims against them under the constitutional iteration of the standing requirement.[38] Each plaintiff has standing, and no claims should be dismissed for lack of standing.

1. The Constitutional Standard for Standing

To have standing a plaintiff must: (i) "demonstrate that he has suffered an 'injury in fact'. . . [that] must be concrete in both the qualitative and temporal sense," *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990); (ii) "satisfy the 'causation' and 'redressability' prongs of the Art. III minima by showing that the injury 'fairly can be traced to the challenged action' and [(iii)] 'is likely to be redressed by a favorable decision.'" *Id.* (quoting *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 38, 41 (1976), and *Valley Forge*, 454 U.S. at 472); *see also American Postal Workers Union v. Frank*, 968 F.2d 1373, 1374 (1st Cir. 1992) (the "standing inquiry has three elements").

At the pleading stage, general factual allegations of injury resulting from the wrongful practice may suffice to establish standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

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[37] Standing arguments are raised by Defendants Abbott, Amgen, AstraZeneca, Baxter, Bayer, Berringer Group, GlaxoSmithKline, Hoffman-LaRoche, Immunex, Johnson & Johnson and related entities, Pfizer, Pharmacia, Sicor, Sicor Gensia and Warrick.

[38] In addition to its constitutional dimensions, "the doctrine of standing also embraces prudential concerns regarding the proper exercise of federal jurisdiction." *United States v. AVX Corp.*, 962 F.2d 108, 114 (1st Cir. 1992). No defendant appears to raise an argument of standing based upon prudential, as opposed to constitutional, concerns.

2. The Allegations Meet the Pleading Standards for Standing

Each individual and corporate plaintiff alleges an injury in fact that fairly can be traced to the challenged action of AWP fraud. Each individual alleges that he or she is a participant in the Medicare Part B system, received one or more pharmaceutical products through that system and incurred payments unlawfully inflated by Defendants. ¶¶ 13-22. Each corporate Plaintiff, too, alleges that it has been billed for and paid charges for covered drugs based on published AWPs. *See* ¶¶ 23-27. Nothing more is required for Article III standing.

The association plaintiffs also meet applicable standards. "The test for associational standing is – like the basic standing requirement – tripartite." *American Postal*, 968 F.2d at 1375. "The plaintiff association must show that (a) at least one of its members possesses standing to sue in his or her own right – *i.e.*, that the member can satisfy the three requirements of injury, tracability and redressability; (b) the interest that suit seeks to vindicate are germane to its purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit" *Id.* (citations omitted); *see also Guckenberger v. Boston Univ.*, 957 F. Supp. 306, 320 (D. Mass.1997) (Saris, J).

Here, each of the 21 associations has alleged that one or more of its members has purchased prescription pharmaceuticals manufactured and/or distributed by Defendants has made inflated payments or co-payments in connection with those purchases, and were injured by the illegal conduct alleged in the Complaint. The associations also briefly describe their organizational purposes, and those purposes are consistent with the interests of this suit. *See, e.g.*, ¶ 28 (Citizens for Consumer Justice is a "Pennsylvania non-profit umbrella organization that promotes affordable, quality health care"); ¶ 29 (Citizen Action of New York is a "coalition of labor, senior citizen, women, student, tenant and community organizations that works with community activists for social and economic justice"). The allegations satisfy the tripartite test for associational standing for each associational plaintiff.

3. Defendants' Argument for More Specifics on Standing Lacks Merit

About half of the Defendants that raise a standing challenge acknowledge that one or more Plaintiffs have specifically identified a particular Defendant and/or its drugs as a source of injury,[39] but they persist with a standing challenge by seeking to have the claims of the ***other*** Plaintiffs dismissed as against them.[40] There is no requirement that every Plaintiff in these consolidated proceedings allege a purchase from every Defendant. The existence of one or more Plaintiffs who have provided the desired specificity is sufficient for standing purposes. *See Houlton Citizens' Coalition v. Town of Houlton*, 175 F.3d 178, 183 (1st Cir. 1999) (courts need not verify the independent standing of other parties when one of several parties, all of whom make similar arguments, has standing). The relief that these Defendants seek – an order limiting the claims against them to some-but-not-all of the Plaintiffs, and some-but-not-all of their drugs – apart from being unworkable, amounts to little more than an effort to de-consolidate these consolidated proceedings. At this stage of these MDL proceedings, nothing is to be accomplished by a series of rulings denominating which Plaintiffs are permitted to sue which Defendants for which drugs.[41]

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[39] Abbott Mem. at 1-2 (acknowledging that United Food and Commercial Workers Unions and Employers Mid West Health Benefits Fund ("UFCW") has a alleged "payment for an Abbott-manufactured drug"); Baxter Mem. at 1-2 (acknowledging that UFCW "alleges that it provided reimbursement for Baxter Therapies"); Boehringer Group Mem. at 4 (acknowledging that UFCW "has specifically alleged an injury fairly traceable to Boehringer"); GlaxoSmithKline Mem. at 1-3 (acknowledging that Teamsters Health & Welfare Fund of Philadelphia "THWF" has alleged purchase of a "prescription drug presently or formally manufactured by GSK"); Immunex Mem. at 2-3 (acknowledging that both UFCW and THWF alleged "payment for and Immunex-Marketed Drug"); Johnson & Johnson Mem. at 4-5 (acknowledging the purchase of Remicade, a drug manufactured by a J&J defendant); Pharmacia Group Mem. at 2-5 (acknowledging that both UFCW and THWF allege "that they paid for Pharmacia products"); SICOR Group Mem. at 1-3 (acknowledging that UFW alleges the purchase of one of SICOR's products"); Warrick Mem. at 1-3 (acknowledging that TCBW alleges a payment for Warrick-manufactured products).

[40] *See, e.g.*, Boeringher Group Mem. at 4 (seeking dismissal of "the claims of all plaintiffs save UFCW"); GlaxoSmithKline Mem. at 1 (seeking "an order limiting the claims against GSK to just one plaintiff asserting over payment to just one drug").

[41] While some Defendants acknowledge that certain Plaintiffs have specifically alleged purchase of that Defendant's drug(s), some Defendants still press dismissal of claims ***even as against that plaintiff*** by arguing that the Complaint fails to allege that those purchases were based on the AWP. *See, e.g.*, Abbott Mem. at 1-2. However, the Complaint specifically alleges that the "Third Party Payor Plaintiffs overpaid for applicable drugs based on, and in reliance on the, AWPs." ¶ 27.

The other Defendants that attack standing argue that the MCC fails to identify a specific Plaintiff that has purchased a specific drug manufactured by that Defendant. The argument fails for several reasons.

First, such specificity is not required at this early pleading stage particularly where, as here, the four third party payor Plaintiffs and the twenty-four associational Plaintiffs represent significant constituencies and have alleged purchases of Defendants' prescription drugs based upon inflated AWPs.[42] Second, submitted affidavits further demonstrate purchases from each Defendant of Defendants' products by Plaintiffs based upon AWPs, and accordingly have established requisite injury traceable to Defendants' challenged conduct.[43]

Third, the Complaint alleges a common practice among all Defendants by inflating AWPs in an effort to disguise kickbacks and other wrongful remuneration, and Defendants are thereby "juridically linked" purposes of this case. *See Payton v. County of Kane*, 308 F.3d 673, 678-680 (7th Cir. 2002) (six named plaintiffs that have direct claims against only two defendants nevertheless have standing to bring an action against all 19 defendants whose common course of action was juridicially linked); *see also Fallick v. Nation Wide Mutual Insurance Co.* 162 F.3d 410, 423 (6th Cir. 1998) (using juridical link analysis, the court concluded that once a plaintiff had established a claim against one of the named defendants, the rest of the determination about the suitability of class certification should proceed as usual under Rule 23, not as a matter of standing); *Moore v. Comfed Sav. Bank*, 908 F.2d 834, 838-39 (11th Cir. 1990) (it is appropriate to join as defendants even parties with whom the named class plaintiffs did not have direct

[42] At the pleading stage, general factual allegations of injury resulting from Defendants' conduct may suffice to establish standing. *Lujan v. Defenders of Wildlife*, 504 U.S. at 561. In this case, each of the four Third Party Payor Plaintiffs and each of the twenty-one non-profit association Plaintiffs, have hundreds or thousands of members that include members who have purchased prescription pharmaceuticals and made payments or co-payments and were injured by inflated AWPs. The fair inference is that Plaintiffs or their members have purchased drugs for all Defendants, just as the Complaint alleges.

[43] *See* Exhibits 3 to 26 attached to the Affidavit of Thomas M. Sobol. Defendants raise a standing challenge under both Rule 12(b)(1) and 12(b)(6). The First Circuit has not decided whether a motion to dismiss for lack of standing falls under rule 12(b)(1) or 12(b)(6). Compare *Sea Shore Corp. v. Sullivan*, 158 F.3rd 51, 54 (1st Cir. 1998) (standing as jurisdictional), with *Benjamin v. Aroostook Med. Ctr., Inc.*, 57 F.3rd 101, 104 (1st Cir. 1995) (standing analysis "differs little" from 12(b)(6) standard). A court may, however, receive evidence other than the allegations of a complaint when standing is challenged. *See New Hampshire Right to Life PAC v. Gardner*, 99 F.3d 8, 12 (1st Cir. 1996).

contact, and accordingly joinder by the court *sua sponte* of defendants that did not extend loans or otherwise have dealings directly with the plaintiff was proper under Rule 20); *Alves v. Harvard Pilgrim Health Care, Inc.*, 204 F. Supp. 2d 198, 205 (D. Mass. 2002) (Saris, J.) (citing *Fallick* and concluding that claims of ERISA beneficiaries could be maintained against two entities even though no plaintiff was a member of a plan with those entities).

In this case, it is ironic that Defendants themselves present the juridical link through their common defense that their collective actions are lawful and sanctioned by federal statute and/or regulation. Finally, Defendants' standing challenge really amounts to an attack on the representativeness or typicality of claims each named plaintiff as against them; those issues are far better dealt with at the Rule 23 stage.

B. ERISA Plans Are Proper Plaintiffs

Defendant Abbott asserts that the claims brought by plaintiffs Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund ("CMHV"), Teamsters Health & Welfare Fund ("THWF"), Twin Cities Bakery Workers Health and Welfare Fund ("TCBW") and United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") should be dismissed under Rule 17(a), arguing that these plaintiffs are not real parties in interest with authority to bring suit on their own behalf. Abbott is wrong.

These four employee welfare benefit plans ("EWBP"s) are established and maintained pursuant to ERISA for the purpose of providing health benefits to eligible participants and beneficiaries. ¶¶ 23-26. Yet, EWBPs have the right to sue and be sued like other corporations and legal entities in non-ERISA contexts. *See* 29 U.S.C. §1132(d)(1); *Local 159 v. Nor-Cal Plumbing, Inc.*, 185 F.3d 978, 983 (9th Cir. 1999) (citing *Pressroom Unions-Printers League Income Sec. Fund v. Continental Assurance Co.*, 700 F.2d 889, 893 n. 8 (2d Cir. 1983)); *Int'l Union of Bricklayers & Allied Craftsmen, Local #1 v. Menard & Co. Masonry Bldg. Contractors*, 619 F. Supp. 1457, 1462 (D.R.I. 1985). Thus, although Abbott may be correct in stating that EWBPs are trusts, the whole crux of §1132(d)(1) in conferring legal entity status on

EWBPs is to "eliminate[] an artificial impediment to the prosecution of actions by such a fund . . . and thereby enhance[] an important purpose of ERISA: furtherance of the stability and integrity of [EWBPs]." *Int'l Union of Bricklayers*, 619 F. Supp. at 1462 (distinguishing *Carpenters & Millwrights Health Benefit Trust Fund v. Domestic Insulation Co.*, 387 F. Supp. 144, 147 (D. Colo. 1975).[44] Accordingly, the Court should reject Abbott's argument.

C. The Filed Rate Doctrine Does Not Apply Here

Defendants BMS and Braun contend that Plaintiffs' Class 1 claims are barred by the filed rate doctrine because the Medicare reimbursement rates at issue "were determined by the government." BMS Mem. at 1, 5; *see also* Braun Mem. at 1, 5-7. However, the filed rate doctrine does not apply here because the AWPs reported by Defendants were not filed with, approved or even reviewed by any regulatory body.

The filed rate doctrine prohibits a regulated entity from charging rates other than those "properly filed with the appropriate federal regulatory authority." *Arkansas La. Gas Co. v. Hall*, 453 U.S. 571, 577 (1981). The doctrine applies to industries that are statutorily required to file schedules of tariffs and rates with a regulatory body, such as public utilities, telecommunications, and shipping carriers. *See Town of Norwood v. New England Power Co.*, 23 F. Supp. 2d 109, 116 n.6 (D. Mass. 1998) (Saris, J.), *rev'd in part on other grounds*, 202 F.3d 408 (1st Cir. 2000). Information that is not "filed" with a governing regulatory agency pursuant to a legal obligation is not immunized under the filed rate doctrine and does not carry the force of law. *Comsource Indep. Foodservice Co. v. Union Pacific R.R.*., 102 F.3d 438, 442 (9th Cir. 1996) (holding that the filing of a tariff gives constructive notice of only those terms that are required to be filed in the tariff).

[44] Significantly, Abbot does not cite any authority that directly supports its proposition. *Lenon v. St. Paul Mercury Ins. Co.*, 136 F. 3d 1365 (10th Cir. 1998), did not address whether EWBPs were real parties in interest and/or could sue in their own right. Rather, the question was whether ERISA plans were trusts. As *International Union of Bricklayers* makes clear, though ERISA plans may be trusts, they still may sue and/or be sued. Indeed, even *Lenon* conceded that ERISA plans could sue in their own right and on their own behalf. *See Lenon*, 136 F.3d at 1370 ("We cannot see how the power of participants ***or the plans themselves*** to initiate civil actions in limited circumstances can deprive an ERISA plan of its status as a trust."). *Yale Fin. Servs. Trust v. Palmetto Tomato Packers, Inc.*, 1987 U.S. Dist. Lexis 10886 (N.D. Ill. Nov. 18, 1987), also relied on by Abbott, is distinguishable, as it did not involve an ERISA plan and thus did not call into question the construction of § 1132(d)(1).

Defendants do not file their AWPs with HCFA or any other government agency. First, Medicare reimbursement is based on publicly available published AWPs, not on any specific AWP filed with HCFA or any other regulatory body. Second, the Medicare Act does not require Defendants to file their AWPs with any regulatory body for approval; nor does the Act even require Defendants to submit AWPs to the *Red Book* or other industry compendia. Defendants admit this when they proclaim that "there are no regulations directing [them] to report AWPs to the services that publish them, let alone describing how AWPs are to be calculated." Defs.' Mem. at 4-5. Third, neither the HCFA nor the publishers of industry compendia review, even for accuracy, the AWPs reported by Defendants. *See* ¶ 135. Indeed, Defendants have gone to great lengths to keep the actual AWPs of their respective drugs secret and confidential. Thus, the filed rate doctrine cannot apply.

Knowing this, BMS and Braun attempt to concoct a new filed rate rule that no Court has ever endorsed. Without citing a single case, Defendants argue that the filed rate doctrine should apply by ***fiat*** to the Medicare Act because the doctrine purportedly applies to every regulated industry. *See* BMS Mem at 5; Braun Mem. at 5-6. However, the doctrine applies only to industries that are required to ***file*** schedules of tariffs and rates with a federal agency. *Town of Norwood v. New England Power Co.*, 23 F. Supp. 2d 109, 116 n.6 (D. Mass. 1998). Indeed, no court ever has applied the filed rate doctrine to Medicare because the reimbursement program has no such filing requirements.

BMS and Braun next contend that the doctrine should apply because Medicare Part B requires beneficiaries to pay a percentage of the "'allowed amount' set by Medicare," and that the AWPs constitute a filed rate. Defendant Braun appears to contend that the filed rate consists of the additional component of the 20% co-payment beneficiaries must make to purchase covered drugs. Braun Mem. at 5-6. This argument is easily refuted. The statute provides that the 20% co-payment is merely the beneficiary's fixed percentage of liability and not the amount of the reimbursement cost; it simply cannot constitute a rate or tariff filed with a federal agency.

In any event, the Complaint does not challenge the 20% co-payment amount. And, again, BMS and Braun ignore the fact that AWPs are not filed with a government entity.

Defendants' reliance on this Court's *Town of Norwood* decision is misplaced. Unlike here, *Norwood* involved a defendant utility company that ***had filed*** its rates and termination charges with the regulatory agency that had the exclusive legislative authority to determine whether the wholesale rates were "just and reasonable." 202 F.3d at 418. Nor does this case resemble *Servais v. Kraft Foods, Inc.*, 631 N.W.2d 629 (Wis. Ct. App. 2001), *aff'd*, 643 N.W.2d 92 (2002), cited by Braun as "strikingly similar" to the current situation. Braun Mem. at 7. That court found that the filed rate doctrine applied because the milk prices at issue were "established by a federal agency through formal rulemaking designed to implement a congressional scheme." *See Servais*, 631 N.W.2d at 634-35. The *Servais* court found highly persuasive that the federal government actually recommends minimum milk prices after a full review and public hearing into current economic and marketing conditions. *Id.* at 632-33. The AWPs that form the basis of Plaintiffs' claims undergo no such scrutiny.[45]

D. The State Action And Noerr-Pennington Doctrines Do Not Apply

Defendant BMS asserts that Plaintiffs' claims must be dismissed because Defendants are immune from liability under the related holdings in *Parker v. Brown*, 317 U.S. 341 (1943), and *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). BMS mischaracterizes those holdings and, in any event, the cases do not apply here.

In *Parker*, the Supreme Court held that "the Sherman Act did not apply to anticompetitive restraints imposed by the States 'as an act of government.'" *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 370 (1991) (quoting *Parker v. Brown*, 317 U.S. at

[45] Other cases cited by Defendants are equally inapposite because they concern regulatory schemes that required regulated entities to file their rates with a government agency and receive approval from that agency before charging the filed rates. *See, e.g., Nantahala Power & Light Co. v. Thornburg*, 476 U.S. 953 (1986) (public utility required to file rates with the Federal Energy Regulatory Commission); *County of Stanislaus v. Pacific Gas & Elec. Co.*, 114 F.3d 858 (9th Cir. 1997) (public utility required to file rates with Federal Energy Regulatory Commission and California Energy Regulatory Administration); *Wegoland Ltd. v. NYNEX Corp.*, 27 F.3d 17 (2d Cir. 1994) (finding that a public telephone utility was required to file rates with the Federal Communications Commission); *Kline & Co. v. MCI Communications Corp.*, 98 F. Supp. 2d 69 (D. Mass. 2000) (same); *Cahnmann v. Sprint Corp.*, 961 F. Supp. 1229 (N.D. Ill. 1997) (same), *aff'd*, 133 F.3d 484 (7th Cir. 1998).

352). Simply put, the *Parker* state action doctrine is construed as creating an exemption or immunity from liability for "activities that might otherwise violate ***federal antitrust law***." *Earles v. State Bd. of Certified Pub. Accountants*, 139 F.3d 1033, 1040 (5th Cir. 1998) (emphasis added; citation omitted). Here, however, Plaintiffs have not asserted any antitrust claims, and Defendant has not pointed to one case in which any court has extended the holding of *Parker* state action doctrine beyond the antitrust context.

BMS also claims that it is immune from liability under the Noerr-Pennington doctrine – a doctrine that has its roots in the Supreme Court's holding in *Eastern R.R.*, and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). Under the doctrine, "antitrust liability cannot be predicated solely on petitioning to secure government action even where those efforts are intended to eliminate competition." *Armstrong Surgical Ctr., Inc. v. Armstrong County Mem'l Hosp.*, 185 F.3d 158 (3d Cir. 1999), *cert. denied*, 530 U.S. 1261 (2000). The doctrine is intended to protect the constitutional right to petition the government unless such activities are shown to be a mere sham. *See Eastern R.R.*, 365 U.S. at 137-38; *Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P.*, 129 F. Supp. 2d 578, 592 (W.D.N.Y.), *aff'd*, 229 F.3d 1135 (2d Cir. 2000). As is the case with the *Parker* state action immunity doctrine, the Noerr-Pennington doctrine really is intended as an exemption from liability in the antitrust context.

However, assuming without conceding that the Noerr-Pennington can properly be applied as an exemption from liability in cases asserting RICO and state unfair and deceptive business practice claims, Noerr-Pennington immunity still would not apply here. Plaintiffs simply do not predicate their claims on any effort by Defendants to petition the government to take action. Noerr-Pennington immunity, therefore, does not apply.

E. Abbott's Assertions Concerning Reimbursement For Its Vancomycin Drug Are Misleading

Abbott asserts that one individual plaintiff could not have paid for vancomycin within the four-year statute of limitations because, according to Abbott, "Medicare ceased covering vancomycin on September 1, 1996." Abbott Mem. at 5 (citing 61 Fed. Reg. 66676, 66684 (Dec

18, 1996)). Abbott's contention ignores Plaintiffs' allegation of fraudulent concealment, which nullifies the four year statute of limitation, and, in any event, is wrong. While Medicare reimbursement for vancomycin "as a durable medical equipment infusion pump benefit" did end, *see* 61 Fed. Reg. at 66684, Medicare coverage for vancomycin administered intravenously by methods other than infusion pump remained in effect.[46]

F. Amgen's Assertions Concerning Reimbursement For Its Epogen Drug Are Misleading

Amgen seeks to mislead the Court regarding Epogen reimbursement, claiming that Epogen is not reimbursed by Medicare based on AWP but, rather, by a specifically established price. Amgen Mem. at 1. The statute cited by Amgen, 42 U.S.C. § 1395 rr (b)(11)(B)(ii), does state that Erythropoietin will be reimbursed at a set fee per 1,000 units when the drug is provided by a "provider of services, renal dialysis facility, or other supplier of home dialysis supplies and equipment." However the immediately preceding section, § 1395 rr (b)(11)(B)(i), states that when the drug is provided by a physician, it ***is*** reimbursed pursuant to the AWP system established by Medicare. Thus, any patient who is a Medicare Part B participant and receives Epogen from his physician will make his co-payment based on an inflated AWP. In addition, as plaintiffs have alleged, Amgen does state an AWP for Epogen, which is paid by non-Medicare Part B patients or their providers. Thus, numerous plaintiffs and Class members pay for Epogen, both in and out of the Medicare Part B context, based on AWP.

G. Plaintiffs Make Sufficient Allegations Of BMS's Intent To Defraud

BMS also asks this Court to find that, as a matter of law, BMS did not intend to deceive anyone when it stated AWPs for its drugs far above the prices it charged its customers. Yet, the Complaint specifically alleges each Defendant's fraudulent intent: "[Defendants] deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause plaintiffs and the Class members to

[46] The relevant regulations cite "insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner." 61 Fed. Reg. at 66684.

overpay for the Covered Drugs." ¶ 159; *see also* ¶¶ 162-65. The Complaint also quotes BMS's own documents to not only negate the impermissible inference BMS wants the Court to draw, but to establish that BMS specifically intended, and knew, that Plaintiffs and Class members would use the inflated AWP as a basis for reimbursement:

> Currently, physician practices can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished." ¶ 242

BMS relies on a case under the False Claims Act, *US ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284 (4th Cir. 2002). There, a contractor was accused of filing false claims when it changed billing and accounting entries from one federal program account to another. The court noted that the contractor changed the entries exactly as directed by the Department of Energy. The Court then joined three other Circuits in finding that a claim made against the government is not "false" under the False Claims Act when the government is ***actually aware of the true facts*** at the time the claim is submitted. Thus, the court wrote, "the governments' knowledge of the facts underlying an allegedly false record or statement can negate the scienter requirement . . . ." *Id.* at 289. *Becker* does not help BMS here because, while the government established the AWP system, there is no evidence that the government, or anyone else, was aware of the true facts surrounding BMS's pricing of its drugs, or approved BMS's fraudulent inflation of its AWP's.[47]

Finally, BMS protests that it would be unfair to allow Medicare beneficiaries to recover when, ostensibly, the federal government itself has no claim for AWP manipulation. BMS offers no support for its assertion, and, as BMS well knows, there is a substantial likelihood that the government can recover. Indeed, the United States recently reached an $875 million criminal

[47] BMS concedes that reliance is not a required element of mail fraud in the First Circuit, but then cites a case that dismissed a RICO claim where the court found that a plaintiff's reliance was unreasonable because the true facts (real estate values and rental rates) were readily available to the plaintiff. *See United States v. Brown*, 79 F.3d 1550, 1559 (11th Cir. 1996).

and civil settlement with TAP pharmaceuticals regarding AWP manipulation, including the resolution of two False Claims Act suits against TAP. ¶¶ 155-56. More directly, BMS has acknowledged that it is currently the subject of a federal criminal investigation relating to AWP manipulation.[48]

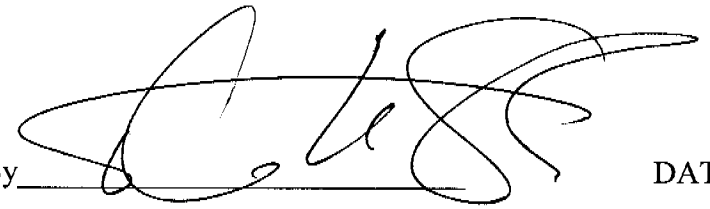
H. Plaintiffs Make Sufficient Allegations Against Defendant Hoffman-La Roche

Plaintiffs allege sufficient facts to state claims against Defendant Roche. Section IV of the Complaint alleges that Defendant Roche engaged in a fraudulent scheme along with every other Defendant. Plaintiffs use the plural to make a complicated factual scenario more comprehensive, not "to tar Roche with the alleged misdeeds of other defendants." *See* Roche Mem. at 4. That Plaintiffs list no "examples" specific to Roche in Section V of the Complaint is irrelevant. Roche also contends that Plaintiffs allege claims against them only as an "afterthought." *See* Roche Mem. at 2 and 5. The fact that Roche was first named in the Complaint and not in any underlying cases transferred by the MDL Panel is irrelevant to whether Plaintiffs state claims against Roche. Roche's earlier omission merely indicates that the investigation of the AWP Scheme is ongoing. Indeed, it is likely that other defendants may be added later.

[48] See BMS' Form 10-Q for the period ending June 30, 2002: "We, together with a number of other pharmaceutical manufacturers, also have received subpoenas and other document requests from various government agencies seeking records relating to its pricing and marketing practices for drugs covered by Medicare and/or Medicaid. . . . We are unable to assess the outcome of these investigations, which could include the imposition of fines, penalties and administrative remedies."

IX. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied.

By  DATED: December 5, 2002.

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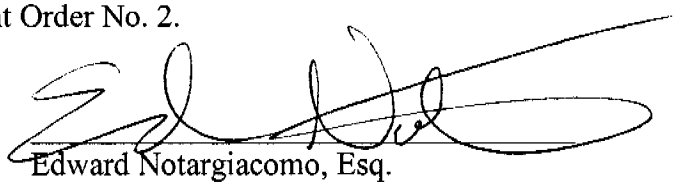
CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused a true and correct copy of the foregoing Plaintiffs' Consolidated Opposition to Defendants' Motions to Dismiss to be served on all counsel of record electronically on December 5, 2002, pursuant to Section D of Case Management Order No. 2.



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